SCIENTIFIC OPINION

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Safety and efficacy of an additive consisting of xanthan gum produced by *Xanthomonas campestris* strains [redacted] for all animal species (Biopolymer International)

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Abstract

Following a request from the European Commission, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on xanthan gum as a feed additive for all animal species. Xanthan gum is manufactured using different production strains belonging to the *X. campestris* species. The identity of the strains producing xanthan gum was not unambiguously established, data on antimicrobial susceptibility were incomplete, and it was not possible to exclude the presence in the additive of viable cells/DNA of the production strains. Consequently, no conclusions could be drawn on the safety of the *X. campestris* strains [redacted]. Considering the above and in the absence of adequate information on the additive under assessment, the FEEDAP Panel cannot conclude on the safety of xanthan gum produced by the *X. campestris* strains [redacted] for the target species, the consumer, the user and the environment. Xanthan gum is considered as an efficacious stabiliser and thickener in feedingstuffs for all animal species at the proposed conditions of use.

Keywords: technological additives, stabiliser, thickener, Xanthan gum, *Xanthomonas campestris*, safety, efficacy

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1831/2003[1] establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 10(2) of that Regulation also specifies that for existing products within the meaning of Article 10(1), an application shall be submitted in accordance with Article 7, at the latest one year before the expiry date of the authorisation given pursuant to Directive 70/524/EEC for additives with a limited authorisation period, and within a maximum of seven years after the entry into force of this Regulation for additives authorised without a time limit or pursuant to Directive 82/471/EEC.

The European Commission received a request from Biopolymer International[2] for re-evaluation of the product xanthan gum, when used as a feed additive for all animal species (category: technological additives; functional group: stabilisers, thickeners).

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) as an application under Article 10(2) (re-evaluation of an authorised feed additive). EFSA received directly from the applicant the technical dossier in support of this application. The particulars and documents in support of the application were considered valid by EFSA as of 3 July 2014.

According to Article 8 of Regulation (EC) No 1831/2003, EFSA, after verifying the particulars and documents submitted by the applicant, shall undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the safety for the target animals, consumer, user and the environment and on the efficacy of the product xanthan gum, when used under the proposed conditions of use (see Section 3.1.4).

1.2. Additional information

Xanthan gum is currently listed in the EU Register of Feed Additives as a technological additive (functional group: emulsifying and stabilising agents, thickeners and gelling agents) for use in feed for all animal species. Xanthan gum is currently authorised as a food additive in accordance with Annex II to Regulation (EC) No 1333/2008[3]. Specific purity criteria on xanthan gum (E 415) have been defined in Commission Regulation (EU) No 231/2012[4].

Xanthan gum has not been previously assessed by EFSA as a feed additive. It has been assessed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 1987, 2016) and by the Scientific Committee for food (SCF, 1992) and was considered safe for use in food. The EFSA Panel on Dietetic Products, Nutrition and Allergies) (NDA) delivered two opinions on health claims for xanthan gum (EFSA NDA Panel, 2010, 2011). The EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) delivered an opinion on the safety of xanthan gum as a food additive, concluding that there is no need for a numerical acceptable daily intake (ADI) (EFSA ANS Panel, 2017).

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier[5] in support of the authorisation request for the use of Xanthan gum as a feed additive.

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA or other expert bodies, peer-reviewed scientific papers, other scientific reports, to deliver the present output.

[1] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.
[2] Biopolymer International, Avenue de Tervueren 13 A, 1040, Brussels.
[3] Regulation (EC) no 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives.
[4] Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.
[5] FEED dossier reference: FAD-2010-0250.

EFSA has verified the European Union Reference Laboratory (EURL) report as it relates to the methods used for the control of xanthan gum in animal feed. The Executive Summary of the EURL report can be found in Annex A.[6]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of Xanthan gum is in line with the principles laid down in Regulation (EC) No 429/2008[7] and the relevant guidance documents: Guidance on technological additives (EFSA FEEDAP Panel, 2012a,b,c), Guidance on studies concerning the safety of use of the additive for users/workers (EFSA FEEDAP Panel, 2012a,b,c), Guidance on the assessment of bacterial susceptibility to antimicrobials of human and veterinary importance (EFSA FEEDAP Panel, 2012a,b,c), Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017a,b,c), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017a,b,c), Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018a,b) and Guidance on the assessment of the safety of feed additives for the environment (EFSA FEEDAP Panel, 2019).

3. Assessment

The additive under assessment is xanthan gum produced by different strains of *Xanthomonas campestris* intended to be used as a technological feed additive (functional groups: stabilisers, thickeners) in feedingstuffs for all animal species.

3.1. Characterisation

3.1.1. Characterisation of the production strains

The additive under assessment is produced by four manufacturing companies,[8] each using a different production strain belonging to the species *X. campestris*. All production strains are deposited in internationally recognised culture collections (Table 1). According to the applicant, all the production strains derived from *X. campestris* pv.*campestris* [redacted][9]

Table 1: *Xanthomonas campestris* production strains under assessment

Accession number	Culture collection
[redacted](a)	[redacted]
[redacted](b)	[redacted]
[redacted](c)	[redacted]
[redacted](d)	[redacted]

(a): Technical dossier/Supplementary information February 2017/Annex VII [redacted]
(b): Technical dossier/Supplementary information December 2015/Annex IV [redacted]
(c): Technical dossier/Supplementary information December 2015/Annex IV [redacted].
(d): Technical dossier/Supplementary information December 2015/Annex IV [redacted].

According to the applicant, all the strains are identified as *X. campestris* but data supporting the taxonomic identification were not provided.[10] No information was provided regarding the history of modifications for strains [redacted], including mutation or genetic

[6] The full report is available on the EURL website: https://ec.europa.eu/jrc/sites/jrcsh/files/finrep-fad-2010-0250-xanthan_gum.pdf
[7] Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. OJ L 133, 22.5.2008, p. 1.
[8] [redacted]
[9] Technical dossier/Section II and Supplementary information December 2015/Supplementary information on xanthan gum as feed additive for EFSA _002_.
[10] Technical dossier/Section II/Sect II Identity, Supplementary information December 2015/Supplementary information on xanthan gum as feed additive for EFSA _002 and Supplementary information February 2017/Annex I - Submission of additional data for xanthan gum reevaluation in feed _ [redacted] _11.16.

modification. [redacted][11]

The applicant stated that the strains of *X. campestris* under assessment do not harbour any plasmids with antibiotic resistance determinants, and if present, these are intrinsic to the species. However, no evidence to support this statement was provided.

The antimicrobial susceptibility was only determined for the production strain [redacted][12] Therefore, due to the paucity of data, the Panel cannot conclude on the antimicrobial susceptibility of the production strains.

3.1.2. Manufacturing process

Details of the production methods used by each manufacturing company were provided [redacted][13]

3.1.3. Characterisation of the additive

The additive consists of pure xanthan gum. Xanthan gum (CAS number 11138-66-2, EINECS number 234-394-2) is a solid additive, marketed in the form of white/beige powder. It has a viscosity of > 600 mPas and a bulk density of 650–850 kg/m^3. It is fully soluble in water.

Xanthan gum is a high molecular weight (~ 1,000,000 Da) polysaccharide and is mainly constituted by D-glucose and D-mannose as the dominant hexose units, along with D-glucuronic acid and pyruvic acid, and is prepared as the sodium, potassium or calcium salt. The primary structure consists of repeated pentasaccharide units formed by two glucose units, two mannose units, and one glucuronic acid unit in a 2.8:2.0:2.0 molar ratio. The main chain of the polysaccharide is composed by β-D-glucose units linked at the 1 and 4 positions with a chemical structure identical to that of cellulose. Side chains of trisaccharides containing a D-glucuronic acid unit between two D-mannose units are linked at the O-3 position of every other glucose residue in the main chain. Approximately half of the terminal D-mannose units form an acetal in 4 and 6 position with the ketone group of pyruvic acid while the D-mannose units linked to the main chain contain an acetyl group at position O-6.

Xanthan gum as a feed additive is specified to be manufactured to meet the specifications set for its use as a food additive. The specifications for xanthan gum as food additive listed in Regulation (EC) No 231/2012[14] are as follows:

- identification: yields, on dried basis, not less than 4.2% and not more than 5% of CO_2 corresponding to between 91% and 108% of xanthan gum;
- purity: pyruvic acid ≥ 1.5%, loss on drying ≤ 15% (105 °C, 2.5 h), total ash ≤ 16% (determined at 650 °C after drying at 105 °C for 4 h), nitrogen ≤ 1.5%, ethanol and propan-2-ol, singly or in combination: ≤ 500 mg/kg.

The analysis of 12 batches of the feed additive (three batches from four producers) showed compliance with the specifications for pyruvic acid, loss on drying, total ash, nitrogen, ethanol and propan-2-ol.[15] Six additional batches were analysed for monosaccharides content. [redacted]

[11] Technical dossier/Supplementary information December 2015/Annex IV.
[12] Technical dossier/Supplementary information December 2015/Supplementary information on xanthan gum as feed additive for EFSA _002 and Technical dossier/Supplementary information February 2017/Annex I - Submission of additional data for xanthan gum reevaluation in feed _ [redacted] _11.16.
[13] Technical dossier/Supplementary information December 2015/Supplementary information on xanthan gum as feed additive for EFSA _002_ and Technical dossier/Supplementary information December 2015/Annex V.
[14] Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council.
[15] Technical dossier/Section II/Annex_II_1_CoAs_xanthan gum.

[redacted] The carbon dioxide yield was within the range specified for the food additive.[16] [redacted][17]

The analysis of five batches indicated contents on undesirable substances as follows. Lead ranged between < 0.005 (limit of quantification, LOQ) and 1 mg/kg, cadmium and mercury below the limits of detection (LODs of 0.01 and 0.005 mg/kg, respectively) and arsenic ranged between < 0.005 (LOQ) and 0.1 mg/kg.[18] Pesticides (organochlorides, organophosphates and pyrethroids) levels were below the respective LOQ[19] in six batches of the additive.[20] In other three batches,[18] pesticides (organochlorides, organophosphates and pyrethroids) levels were below the respective LOQ,[21] the sum of dioxins and dioxin-like PCBs concentration was < 0.104 ng WHO-PCDD/F-PCB-TEQ/kg, and mycotoxins (deoxynivalenol, zearalenone, aflatoxins (B1, B2, G1, G2), ochratoxin A, fumonisins (B1, B2), HT-2 and T2 toxins) levels were below the respective LODs/LOQs.[22] The residual solvent isopropanol ranged from 37 to 256 mg/kg in 10 batches.[23] None of these impurities are considered as a concern. No information on the presence of lipopolysaccharides or on the possible presence of enzymes from the fermentation process (e.g. amylases, cellulases or proteases) was submitted.

Twelve batches of the feed additive (three batches from four producers) were analysed for microbial contamination. *Salmonella* spp. was not detected in 10 g (six batches) nor in 25 g (six batches) of the additive; *Escherichia coli* was not detected in 5 g (nine batches) or 25 g (three batches) of the additive, yeast and moulds were < 300 CFU/g additive.[15]

Only limited data on the potential presence of viable cells of the production organisms in the final additive were provided [redacted] In brief, results from the analyses of 1 g of one batch produced by strains [redacted] showed no detection of viable cells of the production organism. [redacted] No information on the potential presence of DNA of any production strain in the final additive was provided.

The results of the analysis of dusting potential (Stauber-Heubach method) of three batches of the additive showed an average of 17.2 g/m^3 (range: 17.0–17.4 g/m^3).[25]

3.1.4. Stability and homogeneity

The shelf life of the additive was studied by the chemical analysis of its composition and of the maintenance of its technological effect.[26] Six batches of the additive were stored in cans for five years at room temperature. At the time of manufacturing, samples of each batch were collected and analysed for pyruvic acid (4.9%), loss on drying (6.5%), ash (9.9%), nitrogen (0.7%), isopropanol (57 mg/kg), degree of whiteness (82) and pH (7.1). After approximately 12, 24, 36, 48 and 60 months, samples were collected and analysed for the same parameters. The results showed no differences in any of the parameters over time.

The same batches were used to study the stability in water, preparing a solution of 1% xanthan gum in a 1% KCl water solution at 24°C or 66°C; each solution was stirred for 2 h at 800 rpm. Viscosity was then measured using a rotating viscosimeter at 60 rpm and 24°C. No differences in viscosity (~ 1,500 mPas) were observed over time.

For technological additives, stability in feedingstuffs can be demonstrated by persistence of the intended technological effect, and no demonstration of homogenous distribution is considered

[16] Supplementary Information December 2015/Annex I.
[17] Supplementary Information December 2017/Annex I.
[18] Supplementary Information December 2015/Annex II.
[19] LOQ (in mg/kg) ranged from 0.005 to 0.01 depending on the pesticide considered.
[20] Technical dossier/Section II/Annex_II_3_Pesticide purity_xanthan gum.
[21] LOQ (in mg/kg) ranged from 0.002 to 0.1 depending on the pesticide considered.
[22] LOD/LOQ (in mg/kg) ranged: deoxynivalenol: 0.01–0.5; zearalenone: 0.004–0.005; aflatoxins (B1, B2, G1, G2): 0.001–0.002; ochratoxin A: 0.0002–0.001: fumonisins (B1, B2): 0.005–0.1; HT-2 and T2 toxins: 0.002–0.1.
[23] Technical dossier/Section II/Annex_II_1_CoAs_xanthan gum; Supplementary Information December 2015/Annex II; Supplementary Information December 2015/Annex V.
[24] Technical dossier/SIn_Feb17/Annex I - Submission of additional data for xanthan gum reevaluation in feed _[redacted]_11.16 and Technical dossier/SIn_Feb17/Annex IV Xanthane [redacted].
[25] Supplementary Information December 2015/Annex III.
[26] Technical dossier/Section II/Annex_II_6b 1-4.

necessary if the efficacy of the additive is demonstrated. The applicant provided evidence of the stability and homogenous distribution in feed in the efficacy studies done with several feedingstuffs/ feed materials. The studies are described in the efficacy section (see Section 3.3).

3.1.5. Conditions of use

The additive is intended to be used in feedingstuffs for all animal species, without defining a minimum or maximum content; however, a typical range of use levels of 100–10,000 mg/kg feed is proposed by the applicant.

3.2. Safety

3.2.1. Safety of the production organisms

The four production strains are claimed to belong to the species *X. campestris* which is considered by EFSA to be suitable for the qualified presumption of safety (QPS) approach (EFSA, 2007; EFSA BIOHAZ Panel, 2017) when used for the production of xanthan gum. This approach requires the identity of the strains to be conclusively established and evidence that they do not show acquired antimicrobial resistance determinants for antibiotics of human and veterinary importance.

Insufficient information was provided to unambiguously establish the identity of the strains, to assess whether they are genetically modified, to demonstrate the absence of acquired antimicrobial resistance genes to clinically relevant antimicrobials or to exclude the potential presence of viable cells of the production strains or their DNA in the final additive. Therefore, the qualifications for the QPS approach to safety assessment have not been met and thus, it cannot be applied.

Consequently, no conclusions can be drawn on the safety of the use of the *X. campestris* strains [redacted] in the production of the xanthan gum under assessment.

3.2.2. Safety for the target species

No specific tolerance studies in target species with the additive(s) under assessment were provided. Instead, the applicant made reference to several publications describing subchronic (Robbins et al., 1964) and chronic (Woodard et al., 1973) toxicity studies in dogs and acute (Eastwood et al., 1987; Edwards and Eastwood, 1995), subchronic (Booth et al., 1963) and chronic (Woodard et al., 1973) studies in rats. However, these studies showed several limitations in the design or reporting, e.g. number of animals limited (Robbins et al., 1964; Woodard et al., 1973) or not reported (Booth et al., 1963), limited set of parameters analysed (Edwards and Eastwood, 1995). The FEEDAP Panel in addition noted that, when the safe level in feed for the target species is calculated based on the NOAELs identified by the authors in these studies (range: 500–1,000 mg/kg body weight (bw) per day) and following the Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017a,b,c), the safety of the additive for the target species at the maximum proposed inclusion level of 10,000 mg xanthan gum/kg feed is not supported.

Considering the above and the fact that the safety of the production strains has not been established (see Section 3.2.1), the FEEDAP Panel cannot conclude on the safety of xanthan gum produced by the *X. campestris* strains [redacted] for the target species.

3.2.3. Safety for the consumer

Xanthan gum is not absorbed as such in the gastrointestinal tract of rats, dogs and cats, but can be partly fermented in the gut to short-chain fatty acids (Booth et al., 1963; Sunvold et al., 1994, 1995a, b; Edwards and Eastwood, 1995). Xanthan gum fermentation products will be metabolised following the normal metabolic pathways of such substances. Although no information is available on the fate of the additive in the rumen, it is not expected that any unmetabolised xanthan gum would be absorbed and enter the circulation. Deposition of xanthan gum or its fermentation by-products in animal tissues and products is considered unlikely. No exposure of the consumer is expected. Therefore, the use of xanthan gum per se in animal nutrition is not expected to pose a risk for the consumer.

However, the uncertainties linked to the production strains (see Section 3.2.1) do not allow the Panel to conclude on the safety of the additive(s) under assessment for the consumer.

3.2.4. Safety for user

No information was submitted on the effects of the additive(s) under assessment on the respiratory track or on eyes or skin of people exposed to it. Considering the dusting potential of the additive (17.2 g/m^3), exposure via inhalation is likely.

Considering the above and the uncertainties linked to the production strains (see Section 3.2.1), the Panel cannot conclude on the safety for the user of the additive(s) under assessment.

3.2.5. Safety for the environment

Xanthan gum is expected to be almost quantitatively excreted unmetabolised in non-ruminants, while no information on the metabolism in ruminant is available. Xanthan gum could be metabolised in the soil by bacterial enzymatic reactions (Nankai et al., 1999). However, no specific information on the safety for the environment of the additive under assessment was made available.

Due to lack of data, it is not possible to conclude on the safety of the production strains or on the potential presence of viable cells of the production strains/DNA in the final product. In addition, the Panel notes that *X. campestris* pv. *campestris* is a known plant pathogen described as causing a vascular disease of *Brassica* spp. Therefore, no conclusions on the safety of xanthan gum produced by the *X. campestris* strains [redacted] for the environment could be drawn.

3.3. Efficacy

Xanthan gum is authorised for use as a food additive in a range of products with different moisture content. The effect seen when used in food could reasonably be expected to be seen when used in feed at the recommended concentration. The applicant provided a series of studies to support the efficacy done with different feedingstuffs/feed materials.

In the first study,[27] aqueous solutions of xanthan gum (1% solution) were prepared using synthetic tap water (1 L distilled water, 1 g NaCl and 0.15 g $CaCl_2{\cdot}2H_2O$). The solutions were autoclaved, aliquoted and stored at 25°C and at 40°C. Viscosity of solutions was measured after one, two and three months using a rotating viscosimeter at 60 rpm and 24°C. No differences in viscosity (~ 1,200 mPas) were observed in any sample at any time point.

In a second set of studies,[28] four commercial feed products containing xanthan gum (a complete pet food for cats, a milk replacer for piglets, a liquid supplement for lactating cows and a fish feed gel) were used. The cat food was supplemented with 5,100 mg xanthan gum/kg feed, the fish feed gel with 2,500 mg xanthan gum/kg feed. The concentration of xanthan gum in the other two feeds (milk replacer for piglets and liquid supplement for cows) was not known and therefore these two feeds were not further considered.

Ten samples of the commercial canned feed for cats, stored at room temperature for three months, were analysed monthly for texture (using a consistometer which measures the length of the feed which flows in the apparatus) and for viscosity of the gravy (using a rotating viscosimeter at 60 rpm and 24°C). No differences were observed over time (starting values: texture: 2.775 cm and viscosity: 3,203 mPas; vs end values: texture: 2.95 cm and viscosity: 3,258 mPas).[29]

In the second experiment, two batches of commercial fish feed powder were used. From one batch, the powdered feed was rehydrated (75 g feed and 175 g of boiling water), resulting in a gel. Ten samples of the resulting feed were analysed for its texture immediately after preparation, and after 1 or 4 days of storage at 4°C. In addition, subsamples were stored at –20°C for one, two, three or four months. At each timepoint, the samples were analysed after thawing, 1 and 4 days. With the second batch, the same procedure was followed, but feed was stored frozen for two months. The samples were analysed with a Texture Analyser (plunger of 50 mm, speed 1 mm/s and depth 13 mm). The results showed no differences in the texture of the sample at any timepoint (first batch = 1,016 g and second batch = 1,018 g).[30]

In addition, two studies with model feedingstuffs were prepared.[29] In the first one, a model feedingstuff for dogs/cats was prepared, using water, beef chunks, yeast extract, molasses, vitamins

[27] Technical dossier/Section II/Annex II 6c FEED Stability.
[28] Technical dossier/Supplementary Information December 15/Annex VI.
[29] Technical dossier/Supplementary Information December 15/Annex VI/Annex VI_Stability_Study details_xanthan gum.pdf
[30] Technical dossier/Supplementary Information December 15/Annex VI/Annex VI_Stability_Fish Feed Powder label.pdfand Annex VI_Stability_Study details_xanthan gum.pdf

and minerals and the additive was included at 0 or 5,000 mg/kg. The feed was stored in glass bottles for three months, at room temperature (five samples) or at 40°C (five samples). After manufacturing, a visual analysis showed that in the samples prepared without xanthan gum all the meat chunks were at the bottom of the glass bottles; on the contrary, in those with the additive were evenly distributed. After the storage, the visual aspect of the samples was maintained; the gravy of the samples was analysed for viscosity (using a rotating viscosimeter at 12 rpm at room temperature). There was no difference in the values after manufacturing and after three months storage (average value at 25°C: 2,212 mPas; average value at 40°C: 2,197 mPas).

In the second study, a model of complementary feed for all animal species, manufactured with water, sea algae flour, yeast extract, vitamins and minerals, supplemented with 0 or 2,500 mg xanthan gum/kg feed, was stored at room temperature or at 40°C for three months (five samples each), and visually analysed for particles distribution and for viscosity (using a rotating viscosimeter at 30 rpm at room temperature). The visual analysis showed an even distribution of the particles in the supplement feed, and an accumulation of the particles at the bottom of the bottle in the untreated feed. The results of the viscosity analysis showed no differences in the values after manufacturing and after three months storage (average value at 25°C: 130 mPas; average value at 40°C: 128 mPas).

3.3.1. Conclusions on efficacy

Xanthan gum is authorised for use as a food additive in a range of products with different moisture contents, therefore the same effect seen when used in food could reasonably be expected to be seen when used in feed at the recommended concentration. The results of the efficacy studies done in several feedingstuffs confirmed that xanthan is an efficacious stabiliser and thickener in feedingstuffs, at the proposed conditions of use.

4. Conclusions

Xanthan gum is manufactured using different production strains belonging to the species *X. campestris*. The identity of the strains producing xanthan gum was not unambiguously established, data on antimicrobial susceptibility were incomplete, and it was not possible to exclude the presence of viable cells/DNA of the production strains in the additive produced from all companies. Consequently, no conclusions could be drawn on the safety of the *X. campestris* strains [redacted]

Considering the above and in the absence of adequate information on the additive under assessment, the FEEDAP Panel cannot conclude on the safety of xanthan gum produced by the *X. campestris* strains [redacted] for the target species, the consumer, the user and the environment.

Xanthan gum is considered as an efficacious stabiliser and thickener in feedingstuffs for all animal species at the proposed conditions of use.

5. Documentation as provided to EFSA/Chronology

Date	Event
03/11/2010	Dossier received by EFSA. Xanthar gum. Submitted by Biopolymer International.
11/12/2013	Reception mandate from the European Commission
03/07/2014	Application validated by EFSA – Start of the scientific assessment
22/09/2014	Reception of the Evaluation report of the European Union Reference Laboratory for Feed Additives
07/10/2014	Comments received from Member States
27/11/2014	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: identity of the additive, characterisation of the production strain(s), manufacturing process, physico-chemical proprieties, safety and efficacy*
28/07/2016	Request of supplementary information to the applicant in line with Article 8(1)(2) of Regulation (EC) No 1831/2003 – Scientific assessment suspended. *Issues: characterisation of the additive, characterisation of the active agent, safety for the target species*
14/02/2017	Reception of supplementary information from the applicant - Scientific assessment re-started
24/06/2021	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

References

Booth AN, Hendrickson AP and Deeds F, 1963. Physiologic effects of three microbial polysaccharides on rats. Toxicology and Applied Pharmacology, 5, 478–484.

Eastwood MA, Brydon WG and Anderson DM, 1987. The dietary effects of xanthan gum in man. Food Additives & Contaminants, 4, 17–26.

Edwards CA and Eastwood MA, 1995. Caecal and faecal short-chain fatty acids and stool output in rats fed on diets containing non-starch polysaccharides. British Journal of Nutrition, 73, 773–781.

EFSA (European Food Safety Authority), 2007. Opinion of the Scientific Committee on a request from EFSA on the introduction of a Qualified Presumption of Safety (QPS) approach for assessment of selected microorganisms referred to EFSA. EFSA Journal 2007;5(12):587, 16 pp. https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2007.587

EFSA ANS Panel (EFSA Panel on Food Additives and Nutrient Sources added to Food), Mortensen A, Aguilar F, Crebelli R, Di Domenico A, Frutos MJ, Galtier P, Gott D, Gundert-Remy U, Lambre C, Leblanc J-C, Lindtner O, Moldeus P, Mosesso P, Oskarsson A, Parent-Massin D, Stankovic I, Waalkens-Berendsen I, Woutersen RA, Wright M, Younes M, Brimer L, Christodoulidou A, Lodi F, Gelgelova P and Dusemund B, 2017. Scientific Opinion on the re-evaluation of xanthan gum (E 415) as a food additive. EFSA Journal 2017;15(7):4909, 47 pp. https://doi.org/10.2903/j.efsa.2017.4909

EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), Ricci A, Allende A, Bolton D, Chemaly M, Davies R, Girones R, Herman L, Koutsoumanis K, Lindqvist R, Nørrung B, Robertson L, Ru G, Sanaa M, Simmons M, Skandamis P, Snary E, Speybroeck N, Ter Kuile B, Threlfall J, Wahlström H, Cocconcelli PS, Klein G, Prieto Maradona M, Querol A, Peixe L, Suarez JE, Sundh I, Vlak JM, Aguilera-Gómez M, Barizzone F, Brozzi R, Correia S, Heng L, Istace F, Lythgo C and Fernández Escámez PS, 2017. Scientific Opinion on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA. EFSA Journal 2017;15(3):4664, 177 pp. https://doi.org/10.2903/j.efsa.2017.4664

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012a. Guidance for the preparation of dossiers for technological additives. EFSA Journal 2012;10(1):2528, 23 pp. https://doi.org/10.2903/j.efsa.2012.2528

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012b. Guidance on the assessment of bacterial susceptibility to antimicrobials of human and veterinary importance. EFSA Journal 2012;10(6):2740, 10 pp. https://doi.org/10.2903/j.efsa.2012.2740

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012c. Guidance on studies concerning the safety of use of the additive for users/workers. EFSA Journal 2012;10(1):2539, 5 pp. https://doi.org/10.2903/j.efsa.2012.2539

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen G, Aquilina G, Azimonti G, Bampidis V, Bastos ML, Bories G, Chesson A, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, López-Alonso M, López Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Anguita M, Galobart J and Innocenti ML, 2017a. Guidance on the identity, characterisation and conditions of use of feed additives. EFSA Journal 2017;15(10):5023, 12 pp. https://doi.org/10.2903/j.efsa.2017.5023

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen G, Aquilina G, Azimonti G, Bampidis V, Bastos ML, Bories G, Chesson A, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, López-Alonso M, López Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Anguita M, Galobart J, Innocenti ML and Martino L, 2017b. Guidance on the assessment of the safety of feed additives for the target species. EFSA Journal 2017;15(10):5021, 19 pp. https://doi.org/10.2903/j.efsa.2017.5021

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen G, Aquilina G, Azimonti G, Bampidis V, Bastos ML, Bories G, Chesson A, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, López-Alonso M, López Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Anguita M, Dujardin B, Galobart J and Innocenti ML, 2017c. Guidance on the assessment of the safety of feed additives for the consumer. EFSA Journal 2017;15(10):5022, 17 pp. https://doi.org/10.2903/j.efsa.2017.5022

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen G, Aquilina G, Azimonti G, Bampidis V, Bastos ML, Bories G, Chesson A, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, López-Alonso M, López Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Glandorf B, Herman L, Kärenlampi S, Aguilera J, Anguita M, Brozzi R and Galobart J, 2018a. Guidance on the characterisation of microorganisms used as feed additives or as production organisms. EFSA Journal 2018;16(3):5206, 24 pp. https://doi.org/10.2903/j.efsa.2018.5206

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Rychen G, Aquilina G, Azimonti G, Bampidis V, Bastos ML, Bories G, Chesson A, Cocconcelli PS, Flachowsky G, Gropp J, Kolar B, Kouba M, López-Alonso M, López Puente S, Mantovani A, Mayo B, Ramos F, Saarela M, Villa RE, Wallace RJ, Wester P, Anguita M, Galobart J, Innocenti ML and Martino L, 2018b. Guidance on the assessment of the efficacy of feed additives. EFSA Journal 2018;16(5):5274, 25 pp. https://doi.org/10.2903/j.efsa.2018.5274

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis V, Bastos ML, Christensen H, Dusemund B, Kouba M, Kos Durjava M, López-Alonso M, López Puente S, Marcon F, Mayo B, Pechová A, Petkova M, Ramos F, Sanz Y, Villa RE, Woutersen R, Brock T, Knecht J, Kolar B, Beelen P, Padovani L, Tarrés-Call J, Vettori MV and Azimonti G, 2019. Guidance on the assessment of the safety of feed additives for the environment. EFSA Journal 2019;17(4):5648, 78 pp. https://doi.org/10.2903/j.efsa.2019.5648

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2010. Scientific Opinion on the substantiation of health claims related to xanthan gum and increased satiety (ID 838) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2010;8(2):1481, 13 pp. https://doi.org/10.2903/j.efsa.2010.1481

EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2011. Scientific Opinion on the substantiation of health claims related to xanthan gum and changes in bowel function (ID 837) pursuant to Article 13(1) of Regulation (EC) No 1924/2006. EFSA Journal 2011;9(6):2272, 11 pp. https://doi.org/10.2903/j.efsa.2011.2272

JECFA (Joint FAO/WHO Expert Committee on Food Additives), 1987. Xanthan gum. Toxicological evaluation of certain food additives and contaminants. WHO Food Additives Series 21.

JECFA (Joint FAO/WHO Expert Committee on Food Additives), 2016. Evaluation of certain food additives (Eighty-second Report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 1000, 2016.

Nankai H, Hashimoto W, Miki H, Kawai S and Murata K, 1999. Microbial system for polysaccharide depolymerization: enzymatic route for xanthan depolymerization by Bacillus sp. strain GL1. Applied and Environmental Microbiology, 65, 2520–2526.

Robbins DJ, Moulton JE and Booth AN, 1964. Subacute toxicity study of a microbial polysaccharide fed to dogs. Journal of Food and Cosmetics Toxicology, 2, 545–550.

SCF (Scientific Committee for Food), 1992. Report of the Scientific Committee for Food on a second series of food additives of various technological functions, Opinion expressed 19 October 1990, 26th series. Food science and techniques, 1992.

Sunvold GD, Titgemeyer EC, Bourquin LD, Fahey Jr GC and Reinhart GA, 1994. Fermentability of selected fibrous substrates by cat fecal microflora. Journal of Nutrition, 124, 2721S–2722S.

Sunvold GD, Fahey GC Jr, Merchen NR, Titgemeyer EC, Bourquin LD, Bauer LL and Reinhart GA, 1995a. Dietary fiber for dogs: IV. In vitro fermentation of selected fiber sources by dog fecal inoculum and in vivo digestion and metabolism of fiber-supplemented diets. Journal of Animal Science, 73, 1099–1109.

Sunvold GD, Fahey GC Jr, Merchen NR, Bourquin LD, Titgemeyer EC, Bauer LL and Reinhart GA, 1995b. Dietary fiber for cats: in vitro fermentation of selected fiber sources by cat fecal inoculum and in vivo utilization of diets containing selected fiber sources and their blends. Journal of Animal Science, 73, 2329–2339.

Woodard G, Woodard MW, McNeely WH, Kovacs P and Cronin MTI, 1973. Xanthan gum. Safety evaluation by two-year feeding studies in rats and dogs and a three-generation reproduction study in rats. Toxicology and Applied Pharmacology, 24, 30–36.

Abbreviations

bw	body weight
CAS	Chemical Abstracts Service
CFU	colony forming unit
DM	dry matter
EURL	European Union Reference Laboratory
FAO	Food Agricultural Organization
JECFA	The Joint FAO/WHO Expert Committee on Food Additives
LOD	limit of detection
LOQ	limit of quantification
MIC	minimum inhibitory concentration
NOAEL	no observed adverse effect level
PCB	polychlorinated biphenyl
PCDD/F	polychlorinated dibenzo-*p*-dioxin and dibenzofuran
QPS	qualified presumption of safety
RH	relative humidity
TEQ	toxic equivalents
WHO	World Health Organization

Annex A – Executive Summary of the Evaluation Report of the European Union Reference Laboratory for Feed Additives on the Method(s) of Analysis for xanthan gum

In the current applications authorisation is sought under article 10(2) for Xanthan Gum, under the 'category'/'functional groups' 1(d) and 1(e) 'technological additives'/'stabilisers' and 'thickeners' according to the classification system of Annex I of Regulation (EC) No 1831/2003. Specifically, authorisation is sought for the use of the feed additive for all animal species. Xanthan gum is typically added to influence and stabilize the texture of the wet part of canned feed e.g. for dog or cat. The Applicant stated that the purity criteria set in the Commission Regulation (EU) 231/2012 for the food additive apply also for the feed additive. The applicant did not specify minimum or maximum levels of the product in feed, but states that the levels applied are comparable to the Xanthan gum levels in food for human consumption, ranging from 0.01 to 1.0% w/w. For the characterisation of Xanthan gum the Applicant submitted two internationally recognised monographs (European Pharmacopoeia and FAO JECFA monograph for food additive 'Xanthan gum'). Identification is based on gel formation with Locust bean gum, while characterisation is based on the following quantitative assays: - determining the carbon dioxide yields corresponding to the concentration/purity of Xanthan gum; - pyruvic acid assay; - loss on drying; and - total ash. The resulting values are to be compared against the authorised target values. Even though no performance characteristics are provided, the EURL recommends for official control the above mentioned methods described in the FAO JECFA monographs and recommended by Commission Regulation (EU) 231/2012 to characterise Xanthan gum. Since the accurate quantification of Xanthan gum in feedingstuffs is not achievable experimentally the EURL cannot evaluate nor recommend any method for official control to quantify Xanthan gum in feedingstuffs. Further testing or validation of the methods to be performed through the consortium of National Reference Laboratories as specified by Article 10 (Commission Regulation (EC) No 378/2005) is not considered necessary.